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10/580,033	05/19/2006	Gerard Moinet	MERCK-3172	7568

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EXAMINER

COPPINS, JANET L

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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07/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,033

Applicant(s)

MOINET ET AL.

Examiner

Janet L. Coppins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/1/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27 is/are rejected.
- 7) ☒ Claim(s) 1-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Claims 1-27 are pending in the instant application.

Information Disclosure Statement

2. Applicants' Information Disclosure Statement (IDS), submitted May 19, 2006, has been considered by the Examiner. Please refer to the signed copy of Applicants' PTO-1449 form, attached herewith.

Response to Lack of Unity

3. Applicants' election **with traverse** of Group II, claims 1-27 drawn to compounds, compositions, processes and methods of use of formula (I) wherein "X" is S and R1-R6 do not contain a Het group, and specific compound of 3-[2-(4-chlorophenyl)-2-oxoethoxy] - benzo[b]thiophene-2-carboxylate, in the response filed May 1, 2007, is acknowledged. The Examiner has expanded the elected Group to include Group IV, i.e. all compounds, compositions and methods wherein "X" is S, including Het and non-Het rings for the R1-R6 substituents.
4. Applicants' traversal is on the ground(s) that A) the PTO has not established that it would pose an undue burden to examine the full scope of the claims, and B) the "restriction" within a claim violates *In re Hass*, *In re Weber*, and MPEP § 803.02.
5. Regarding A) above, the Examiner reminds Applicants that the instant application was filed under 35 U.S.C. 371 and not 35 U.S.C. 121, and therefore PCT Lack of Unity rules apply rather than Restriction Practice of MPEP 800. Accordingly, burdensome search is not one of the criteria for determining Lack of Unity.
6. Regarding B) above, this is not found persuasive because under PCT Rule 13.1:

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

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Applicants' instant claims do not relate to a single invention, the application is drawn to multiple product inventions of the Markush group of formula (I). The multiple inventions are not so linked as to form a single general inventive concept because according to PCT Rule 13.2:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B, **Part 1(b)**, indicates that "special technical features" means those technical features that as a whole define a contribution over the prior art.

Annex B, **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

Annex B, **Part 1(e)**, indicates the permissible combinations of different categories of claims. **Part 1(e(i))** states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, **Part 1(f)** indicates the "Markush practice" of alternatives in a single claim. **Part 1(f(i))** indicates the technical interrelationship and the same or corresponding special technical feature is considered to be met when: (A) all alternatives have a common property or

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activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B) in Annex B, **Part 1(f)(i-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f(iv))** indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. **Part 1(f(v))** indicates that when dealing with alternatives, it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered, but does not imply that an objection shall be raised.

7. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2, since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a 2-methanone-benzo(thiophene or furan) moiety in common, which does not define a contribution over the prior art (**variables excluded**). Attached to the instant office action is a copy of a reference that provides that the technical feature, which can be taken as a whole amongst all the alternatives, as depicted above, is not a 'special technical feature' as defined in PCT Rule 13.2, by failing to define a contribution over the prior art, as it was known in the art

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prior to the filing of the instant application. Please refer to the Svoboda et al journal article, which discloses the same "special technical feature," and supports the Examiner's position that Applicants' compounds fail to define a contribution over the prior art. Therefore, since the substituents on the technical feature vary extensively (for example "X" can complete either a benzothiophene ring or a benzofuran ring, and "R1" designates an alkyl-carboxylic acid group or contains any aryl or heteroaryl ring) and when taken as a whole result in vastly different compounds, and unity of inventions is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Furthermore, according to PCT Rule 13.3:

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Therefore, since the claims do not contain a special technical feature, which defines a contribution over the prior art, the Examiner may determine within a single claim that the inventions are not so linked as to form a single general inventive concept.

Therefore, the finding of Lack of Unity is still deemed proper. Accordingly, Groups I and III, now combined, drawn to compounds, compositions, and methods of formula (I) wherein "X" is O, remain withdrawn from consideration.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 22-27 are rejected under 35 U.S.C. 112, first paragraph as being *improper product-use* claims. Specifically, since the claimed inventions are not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth below, one skilled in the art clearly would not know how to use the claimed invention

11. Claims 22-27 also rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claims 22-27 are drafted in terms of the "Use of ...", or "Utilisation of..." but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The Examiner also warns that should claim 22 be amended to recite "A method of using a compound of formula (I)... for the preparation of a medicament...", the claim still lacks any steps involved in the method/ process and would therefore remain indefinite, unless Applicants amend the claim to insert proper steps for reciting a process of preparation.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 22-27 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Objections

14. Claims 1-27 objected to for containing non-elected subject matter, i.e. compounds, compositions, and methods wherein "X" is O.

Conclusion

15. In conclusion, claims 1-27 are pending, claims 1-27 are objected to in part wherein "X" is O; and claims 22-27 are rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

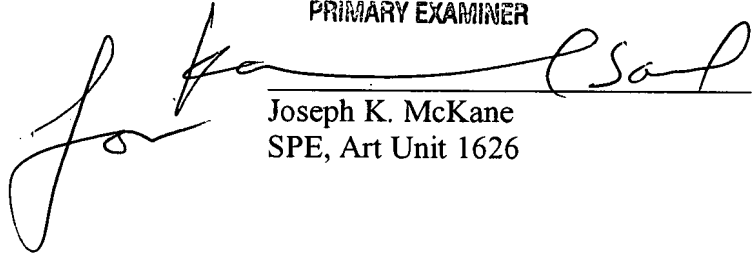
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins
July 15, 2007

KAMALA A. SAEED, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Joseph K. McKane', is written over a horizontal line. The signature is stylized and cursive.

Joseph K. McKane
SPE, Art Unit 1626